

REMARKS

Claims 31, 41, 42 are pending in the application; claims 32-39 and 43 to 61 are withdrawn.

Claim Rejections - 35 U.S.C. 112

Claims 41 and 42 stand rejected under 35 U.S.C. 112, 2nd paragraph, as being indefinite.

It is respectfully submitted that claims 41 and 42 set forth only what type of blood sample or tissue sample is taken for determining receptivity, i.e., claim 31 sets forth in step a) that a blood sample or a tissue sample is taken but does not specify the type of blood or tissue and the dependent claims then define that peripheral blood or endometrial or cervical tissue can be used for determining receptivity in the actual cycle or that menstrual blood can be used for determining receptivity in the subsequent cycle (receptivity in the past is a good indicator that in the future cycle the conditions will be similar).

The claims 41 and 42 have been reworded to avoid confusion as to extra steps.

Reconsideration and withdrawal of the rejection of the claims under 35 USC 112 are respectfully requested.

Rejection under 35 U.S.C. 102

Claim 31 stands rejected under 35 U.S.C. 102(b) as being anticipated by *Bellet et al.* (US 6,194,154).

The examiner argues that all active steps claimed in claim 31 are also disclosed in *Bellet et al.*, i.e., "isolating ..." and "quantitatively measuring ..." are disclosed in *Belklet et al.* and that the added limitation "wherein detection ... indicates receptivity..." does not introduce any active step that distinguishes the invention over the prior art.

The examiner has also stated that the mRNA expression is an inherent property of the endometrium receptive for implantation (page 5, last two paragraphs, of the last office action) and that therefore *Bellet et al.* anticipates the invention as claimed in claim 31 because the detection of β 7-hCG, β 6-hCG, and β 6e-hCG inherently in *Bellet et al.* inherently indicates receptivity.

Claim 31 has been rewritten in view of examiner's remarks so as to define an active step of determining the receptivity. Claim 31 now sets forth in addition to the steps of isolating and quantitatively measuring that the receptivity is determined as follows:

1. no β 7-hCG, β 6-hCG, and β 6e-hCG is detected: the endometrium is not receptive;
2. at least one of β 7-hCG, β 6-hCG, and β 6e-hCG is detected: the endometrium is receptive for implantation.

No such steps are disclosed in *Bellet et al.* and no suggestion that the receptivity of the endometrium could be determined in this way are disclosed or suggested or obvious in view of *Bellet et al.*

Bellet et al. discloses a method for determining the malignant transformation of human cells by comparing the over expression of hCG β 3, β 5, β 8, and β 9-mRNA in malignant mammalian, bladder, thyroid, prostate and colon cells (see Table 3 in col. 8) with the expression of hCG β 7, β 6 in non-malignant (normal) cells of those organs. It is well known that hCG β 3, β 5, β 8, and β 9 are embryonic genes that are not expressed in normal tissue but are switched on in malignant tumors. In normal tissue of the afore mentioned organs hCG β 7, β 6 is expressed; the expression of hCG β 3, β 5, β 8, and β 9-mRNA is an indicator for cancerous growth (see col. 2, lines 26-30) and hCG β 7, β 6 are used as a control. Based on *Bellet et al.*, it is impossible to derive a suggestion that hCG β 7, β 6 is a means for determining the receptivity of the endometrium as there is no mention of the endometrium in connection with expression of hCG β 7, β 6.

Whether hCG β 7, β 6 expression is inherent or not in connection with endometrial changes, the inventors have for the first time recognized that β 7-hCG, β 6-hCG, and/or β 6e-hCG are indicators for the receptivity of the endometrium and have developed the novel and unobvious method as claimed.

Reconsideration and withdrawal of the rejection of the claim 31 under 35 USC 102 are respectfully requested.

Rejection under 35 U.S.C. 103

Claims 41 and 42 stand rejected under 35 U.S.C. 103 (a) as being unpatentable

over *Bellet et al.* and *Acosta et al.*

Claim 31 is believed to be allowable for the reasons presented above and claims 41 and 42 should be allowable as dependent claims.

CONCLUSION

In view of the foregoing, it is submitted that this application is now in condition for allowance and such allowance is respectfully solicited.

Should the Examiner have any further objections or suggestions, the undersigned would appreciate a phone call or **e-mail** from the examiner to discuss appropriate amendments to place the application into condition for allowance.

Authorization is herewith given to charge any fees or any shortages in any fees required during prosecution of this application and not paid by other means to Patent and Trademark Office deposit account 50-1199.

Respectfully submitted on Februar 11, 2008,
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